Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Prophylactic administration of Natural Killer cells early after hematopoietic stem cell transplantation in adult patients with high-risk acute myeloid leukemia

Protocol summary

Study aim

To assess the safety and efficacy of Prophylactic administration of Natural Killer cells early after hematopoietic stem cell transplantation in adult patients with high-risk acute myeloid leukemia

Design

This is a non-randomized, interventional, single-group assignment study to assess the safety and feasibility of an allogeneic NK cell therapy on ten patients with high-risk acute myeloid leukemia who are candidates for allogeneic hematopoietic stem cell transplantation.

Settings and conduct

The study is a single-group clinical trial to evaluate the safety and efficacy of Prophylactic administration of Natural Killer cells early after hematopoietic stem cell transplantation in adult patients with high-risk acute myeloid leukemia at the Hematology-Oncology-Stem Cell Transplantation Research Center (HORCSCT) of Tehran University.

Participants/Inclusion and exclusion criteria

Patients over and equal to 18 years of age with high-risk acute myeloid leukemia who are candidates for allogeneic hematopoietic stem cell transplantation from matched or mismatched donors are included in the study. Patients with uncontrolled infection or severe acute graft-versus-host disease are excluded from the study

Intervention groups

All patients will be assigned to the only interventional arm of the study. Recipients of allogeneic Stem Cell Transplantation will receive the systemic intravenous infusion of natural killer cells at days +6 and +12 post-transplantation.

Main outcome variables

Natural Killer cell infusion-related Adverse Events, Relapse incidence for one year after infusion.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20140818018842N35**
Registration date: **2023-07-13, 1402/04/22**
Registration timing: **prospective**

Last update: **2023-07-13, 1402/04/22**
Update count: **0**

Registration date

2023-07-13, 1402/04/22

Registrant information

Name

Leyla Sharifi Aliabadi

Name of organization / entity

Research Institute for Hematology, Oncology and Stem Cell Transplantation,Tehran University of Medic

Country

Iran (Islamic Republic of)

Phone

+98 21 8490 3691

Email address

ctu@sina.tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-07-23, 1402/05/01

Expected recruitment end date

2023-12-22, 1402/10/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
Prophylactic administration of Natural Killer cells early after hematopoietic stem cell transplantation in adult patients with high-risk acute myeloid leukemia

Public title
Natural Killer cell in acute myeloid leukemia
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Age 18 years old or more Recipients of allogeneic Stem Cell Transplantation for high-risk Acute Myeloid Leukemia by ELN classification Recipients of allogeneic Stem Cell Transplantation from matched or mismatched donors. MRD ≥ 5% after the first Induction or MRD ≥ 0.1% after the second Induction or MRD ≥ 0.01% before transplantation Normal organ function
Exclusion criteria:
Second allogeneic Stem Cell Transplantation Active or uncontrolled infection Acute graft versus host disease
Age
From **18 years** old to **60 years** old
Gender
Both

Phase
1
Groups that have been masked
No information
Sample size
Target sample size: **10**
Randomization (investigator's opinion)
N/A
Randomization description
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not used
Assignment
Single
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethic committee of Hematology- Oncology and Stem Cell Transplantation Research Center, Tehran Univer
Street address
Kargar shomali Ave., Shariati hospital
City
Tehran
Province
Tehran
Postal code
1411713131
Approval date
2022-08-11, 1401/05/20
Ethics committee reference number
IR.TUMS.HORCSCT.REC.1401.011

Health conditions studied

1

Description of health condition studied
acute myeloid leukemia
ICD-10 code
C92.0
ICD-10 code description
Acute myeloblastic leukemia

Primary outcomes

1

Description
Number of Patients With Grades 3-5 of Natural Killer cell infusion-related Adverse Events
Timepoint
Daily during the first seven days after the injection
Method of measurement
History, Physical exam, and lab test

2

Description
Relapse Incidence
Timepoint
one year after infusion
Method of measurement
Bone marrow aspiration and biopsy

Secondary outcomes

empty

Intervention groups

1

Description
All patients are included in the only intervention arm of the study. Patients in the intervention arm will receive two doses of in-vitro expanded NK cells at the 6 and 12 days after transplantation under full supervision and in an isolated room. The process of isolation and preparation of NK cells will be done in a clean room with clinical grade and suitable conditions for producing NK cells. 20 to 30 cc of peripheral blood was taken from the third-party donor and after the isolation of mononuclear cells, CD56+/CD3- reproduced. A viability test is done using trypan blue and phenotyping is used to check the absolute number and purity of cells.

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Hematology- Oncology and Stem Cell Transplantation Research Center, Tehran University of Medical Sci
Full name of responsible person
Maryam Barkhordar
Street address
North Kargar Ave.
City
Tehran
Province
Tehran
Postal code
1417713135
Phone
+98 21 8800 4140
Email
barkhordarm.n@gmail.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Mohamad Ahmadvand
Street address
Kargar-e-Shomali Ave.
City
Tehran
Province
Tehran
Postal code
1411713131
Phone
+98 913 185 6733
Email
ahmadvand.mohamad64@yahoo.com
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Tehran University of Medical Sciences
Proportion provided by this source
100
Public or private sector
Public
Domestic or foreign origin
Domestic
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
Academic

Person responsible for general inquiries

Contact
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Maryam Barkhordar
Position
Associate professor
Latest degree
Subspecialist
Other areas of specialty/work
Hematology
Street address
Kargar-e-Shomali Ave.
City
Tehran
Province
Tehran
Postal code
1411713131
Phone
+98 21 8800 4140
Email
barkhordarm.n@gmail.com

Person responsible for scientific inquiries

Contact
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Mohamad Vaezi
Position
Assistant professor
Latest degree
Subspecialist
Other areas of specialty/work
Hematology
Street address
Kargar-e-Shomali Ave.
City
Tehran
Province
Tehran
Postal code
1411713131
Phone
+98 21 8800 4140
Email
vaezi.mohammad@yahoo.com

Person responsible for updating data

Contact
Name of organization / entity
Tehran University of Medical Sciences

Full name of responsible person
Maryam Barkhordar
Position
Associate professor
Latest degree
Subspecialist
Other areas of specialty/work
Hematology
Street address
Kargar-e-Shomali Ave.
City
Tehran
Province
Tehran
Postal code
1411713131
Phone
+98 21 8800 4140
Email
barkhordarm.n@gmail.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available
Justification/reason for indecision/not sharing IPD
There is no further information
Study Protocol
No - There is not a plan to make this available
Statistical Analysis Plan
No - There is not a plan to make this available
Informed Consent Form
No - There is not a plan to make this available
Clinical Study Report
No - There is not a plan to make this available
Analytic Code
No - There is not a plan to make this available
Data Dictionary
No - There is not a plan to make this available